a first base substrate film comprising a first polymer;

a first deposit, including an active ingredient deposited on a first surface of said first base substrate film and forming a self contained complete single unit form as deposited; and

a cover substrate film comprising a second polymer, the cover substrate film covering the first deposit and joined to said first base substrate film by a first bond that surrounds said deposit, said active ingredient being present in an amount that does not vary from a target amount by more than 5 weight per cent.

REMARKS

Claims 1-10, 17-19 and 21-35 are active. Claims 36-37 are canceled. Claims 1-10, 17-19 and 21-35 are rejected under 35 USC 102.as being anticipated by Mlodozeniec. Claims 36 and 37 are rejected under 35 USC 101.

The rejection based on double patenting is moot as the involved claims are canceled.

Amended claims 1-10, 17-19 and 21-35 are submitted for the Examiner's reconsideration. These claims include certain of the subject matter of canceled claims 36 and 37. While canceled claims 36 and 37 are also rejected as anticipated by Mlodozeniec, applicant disagrees that that subject matter is disclosed by this reference. As discussed in detail below, Mlodozeniec is foreign to the common subject matter of the claims amended herein and the canceled claims. The Office Action does not address the issue discussed below in regard to this common subject matter of claims 36 and 37 which are deemed the same as the claims in the issued patent under 35 USC 101. This issue is also discussed in the file of the parent application forming the basis of allowance of the claims of the parent application.

Attached is a copy of the version of the amended claims showing the changes. The claims are believed allowable.

The claims stand rejected under 35 U.S.C. §102(b) as being anticipated under Mlodozeniec. Applicant appreciates the Examiner's careful thought in formulating the rejection. However, in view of the present amendment to the claims, such rejection now would be incorrect as a matter of law. "To be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure." Chester v. Miller, 906 F.2d 1574, 1577 n.2, 15 USPQ2d 1333, 1336, n.2 (Fed. Cir. 1990) (emphasis added). As will now be explained, Mlodozeniec not only fails to enable, but actually teaches away from, the amended claims.

Claim 1 amended calls for:

> said at least one active ingredient being deposited in separate discrete spaced locations on the substrate, each location comprising the active ingredient present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent. (underlining added)

Mlodozeniec is foreign to this structure. Mlodozeniec discloses the electrostatic deposition of charged pharmaceutical powder onto a moving web. The web is continuously fed along a charged metal surface, and thus moves through a chamber containing a cloud of charged particles. See Fig. 2 and col. 17, lines 30-37. Mlodozeniec regulates the amount of the dosage by varying the feed rate of the charged powder (but not the feed rate of the web) into the deposition chamber. See col. 15, lines 34-41. His purpose in doing this is "to provide a uniformity of flow in order to enable exact and uniform deposition of the active ingredient on the web." See col. 10, lines 66-68 (reference omitted). However the entire web is coated in a film of the active ingredient and not in spaced discrete locations as claimed.

Mlodozeniec, at col. 26, lines 39-59, discloses a potential alternate embodiment. That is, instead of continuously feeding the web through the particle deposition chamber, the active ingredient could be deposited at "short intervals," with the result that the active ingredient could be "spot deposited" and surrounded on all sides by uncoated webs. However, Mlodozeniec admits, in the middle of the disclosure cited, that such "spot deposits" would not provide a "therapeutically efficacious dosage." In Mlodozeniec's own words: "In view of the [shortcomings of his equipment and of his disclosed method], it is preferred to load active substance continuously onto the web in sufficient amount so that the unitizing operation produces dosage forms containing a therapeutically efficacious dosage." See col. 26, lines 48- 54 (emphasis added).

That is, by starting and stopping the movement of the web through the particle-filled deposition chamber, Mlodozeniec could make "spot deposits," but he then would lose the control normally afforded by the continuous movement of the web. Thus, there would be no way for Mlodozeniec to ensure that each of the spot deposits contained the correct amount of drug. Such "spot deposits" certainly would not meet the limitation of the amended claims, wherein "the active ingredient in each deposition is present in an amount that does not vary from a target amount by more than about 5 weight percent. (emphasis added)"

Applicant can find no disclosure in Mlodozeniec of equipment or process conditions that would enable the production of "spot deposits" containing a therapeutically efficacious "target amount" of active ingredient. In view of such non-enablement, Mlodozeniec fails as a §102 reference. Chester v. Miller, supra.

Moreover, Mlodozeniec teaches that, in order to obtain a therapeutically efficacious dosage amount, his method could not be performed at "short intervals," but instead would have to be performed continuously. This would result in a "uniform deposition" across the web, which then would need to be "unitized" (that is, sliced, diced and/or folded) according to Mlodozeniec's central teaching. ("While the methods and equipment . . . may vary somewhat, the overall prime object is uniformity of deposition,

i.e. to deposit active ingredient on the moving web surfac s in an exceptionally uniform manner." See col. 15, lines 64-68 (emphasis added).) Mlodozeniec, by teaching away from the method of forming "spot deposits," thus would fail not only as a §102 reference, but also as a §103 reference. For these reasons, claim 1 is believed allowable.

Claim 6 calls for:

forming a plurality of discrete spaced discrete pharmaceutical or diagnostic unit dosage forms on a substrate

This claim is believed allowable since the Mlodozeniec reference is non-enabling for this step as discussed above.

Claim 17 calls for:

each unit form of the second plurality being deposited in spaced relation to the other unit forms of the second plurality on a substrate

This claim is believed allowable since the Mlodozeniec reference is non-enabling for this structure as discussed.

Claim 21 calls for:

a first deposit, including an active ingredient deposited on a first surface of said first base substrate film and forming a self contained complete single unit form as deposited;

The Mlodozeniec reference does not teach or suggest this structure since an effective single dosage unit can not be formed as an effective self contained complete single unit form as deposited for the reasons discussed above. The reference requires forming a continuous layer and then dicing the layer. This process does not form a self contained complete single unit form as deposited. This is not what is claimed. Claim 21 is believed allowable.

The remaining claims depend from the independent claims and are believed allowable at least for the same reasons.

Since all of the claims have been shown to be in proper form for allowance, such action is respectfully requested.

The Commissioner is authorized to charge or credit deposit account 03-0678 for any under or overpayments in connection with this paper.

Respectfully submitted,
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VERSION SHOWING THE CHANGES TO THE CLAIMS

1 (Twice amended). A product comprising:

a substrate [package]; and

a plurality of discrete pharmaceutical or diagnostic unit dosage forms associated with the substrate [package], each unit dosage form including at least one active ingredient, said at least one active ingredient being deposited in separate discrete spaced locations on the substrate, each location comprising the active ingredient present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent.

2 (Amended). The product of claim 1 [wherein the] further including a package compris[es]ing a container [and] containing the unit forms [are physically separate and independent from one another].

6 (Twice amended). A method of forming a drug dosage or diagnostic product comprising forming a plurality of discrete spaced discrete pharmaceutical or diagnostic unit dosage forms on a substrate, each unit form including at least one active ingredient, said at least one active ingredient being present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent.

17 (Twice amended). A product comprising:

a package; and

a first plurality of diagnostic or pharmaceutically active unit dosage forms associated with the package, a second plurality of unit forms associated with the first

plurality, each unit form of the second plurality being deposited in spaced relation to the oth r unit forms of the second plurality on a substrate, each said unit dosage unit forms including at least one diagnostic or pharmaceutically active ingredient, said at least one active ingredient being present in each of the unit dosage forms in an amount which does not vary from a given target amount by more than a predetermined value.

21 (Amended). A product comprising a pharmaceutical or diagnostic unit form, the unit form comprising:

a first base substrate film comprising a first polymer;

a first deposit, including an active ingredient [disposed] deposited on a first surface of said first base substrate film and forming a self contained complete single unit form as deposited; and

a cover substrate film comprising a second polymer, the cover substrate film covering the first deposit and joined to said first base substrate film by a first bond that surrounds said deposit, said active ingredient being present in an amount that does not vary from a target amount by more than 5 weight per cent.